

Remarks

The amendment to Formulation 9 (page 19, line 10) corrects a typographical error. The weight of Anhydrous Lactose should read "120.0" mg. The quantity of the ingredients (Raloxifene HCL (60.0 mg), Spray Dried Lactose (30.0 mg), Anhydrous Lactose (120.0 mg), Povidone (12.0 mg), Polysorbate 80 (2.4 mg), Crospovidone (14.4 mg), and Magnesium Sterate (1.2 mg)) equal the "Core Tablet Weight" of "240.0" mg. As evidence that this is a typographical error, the quantity of Anhydrous Lactose in Formulation 10 (page 20 of the specification) is "120.0" mg.

Claims 19 and 145-157 are pending.

Claim 145 has been amended and Claim 157 has been cancelled. Claim 145 has been amended by deleting the "55-65 mg" dose and incorporating the "60 mg" dose in dependent claim 157 which now reads "A method for reducing . . . comprises 60 mg of the hydrochloride salt . . ." Support for this claim can at least be found on page 15 line 12. Claims 19, 146-156 remain as dependent claims.

Claims 19, 145-152 have been rejected under 35 § U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,103,740 (Lakshmanan).

Claims 153-156 have been rejected under 35 § U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,103,740 (Lakshmanan) as applied to claims 19 and 145-152 above and in view to U.S. 5,393,763 (Black).

The examiner stated that

Claim 157 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant's prior-filed U.S. Provisional Applications provide support for administration of 60 mg/day raloxifene HCL. Because these prior-filed applications were filed prior to the earliest effective filing date of Lakshmanan, the reference is not available as prior art against claim 157.

35 § U.S.C. 102(e) Rejection

Claims 19, 145-152 have been rejected under 35 § U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,103,740 (Lakshmanan).

It is stated at least on page 10, lines 25-27 of U.S. provisional application 60/029,850 filed Oct 30, 1996 that "[a] preferred dosage range is between about 60 and about 120 mg/day, with 60 mg/day particularly preferred." It is stated at least on page 5, lines 9-11 of U.S. provisional application 60/040,260 filed March 10, 1997 that "[a] preferred dosage range is between about 60

and about 120, or 150, mg/day, with 60 mg/day particularly preferred.” It is stated at least on page 10, lines 25-27 of GB provisional application 9624800.0 filed Nov 29, 1996 that “[a] preferred dosage range is between about 60 and about 120 mg/day, with 60 mg/day particularly preferred.” All provisional applications were filed prior to the provisional application for Lakshmanan (the patent application 09/129,324 which issued as U.S. 6,103,740 claims priority to 60/056,203 filed Aug 21, 1997).

Applicants traverse the examiner’s rejection under 35 § U.S.C. 102(c); however, in the interest of expediting prosecution, Applicants have amended independent Claim 145 to include the preferred 60 mg/day dosage and therefore, submit that the examiner’s current rejection of claims 19, 145-152 as being anticipated by Lakshmanan is moot.

35 § U.S.C. 103(a) Rejection

Claims 153-156 have been rejected under 35 § U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,103,740 (Lakshmanan) as applied to claims 19 and 145-152 above and in view to U.S. 5,393,763 (Black).

Applicants traverse the examiner’s rejection under 35 § U.S.C. 103(a); however, in the interest of expediting prosecution, Applicants have amended independent Claim 145 to include the preferred 60 mg/day dosage and therefore, submit that the examiner’s current rejection of claims 153-156 as being obvious over Lakshmanan and in view of Black is moot.

Further, with regard to the examiner’s presumption of common ownership, the subject matter of the various claims was commonly owned at the time of invention.

Applicants submit that the presently amended claim 145 and claims 19 and 146-156 are in condition for grant.

Respectfully submitted,

/Gary M. Birch/
Gary M. Birch
Agent for Applicants
Registration No. 48,881
Phone: 317-276-0335

Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288

February 18, 2010